

EXHIBIT 6

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL)
5 PRESCRIPTION) MDL No. 2804
6 OPIATE LITIGATION)
7 _____) Case No.
8) 1:17-MD-2804
9)
10 THIS DOCUMENT RELATES) Hon. Dan A.
11 TO ALL CASES) Polster
12)

13 TUESDAY, DECEMBER 11, 2018

14 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
15 CONFIDENTIALITY REVIEW

16 - - -

17 Videotaped deposition of Cathy
18 Stewart, held at the offices of STINSON
19 LEONARD STREET LLP, 7700 Forsyth Boulevard,
20 Suite 1000, St. Louis, Missouri, commencing
21 at 9:03 a.m., on the above date, before
22 Carrie A. Campbell, Registered Diplomat
23 Reporter and Certified Realtime Reporter.

24 - - -

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1 A. I think they were reorganizing
2 the logistics organization under a new vice
3 president, so they were shifting people
4 around, bringing some new people up through
5 the ranks into other positions.

6 Q. Okay. When you moved into the
7 customer service position in approximately
8 2008, who was your predecessor in that
9 position with respect to dosage?

10 A. Sean Welch, W-e-l-c-h.

11 Q. Is that a man or a woman?

12 A. He's a man.

13 Q. Okay. And so did Mr. Welch --
14 do you know why he moved out of that
15 position?

16 MR. DAVISON: Objection to
17 form.

18 THE WITNESS: He left the
19 company to accept another position.

20 QUESTIONS BY MR. GOTTO:

21 Q. Okay. When you moved into the
22 customer service position, was there any
23 training you went through to prepare yourself
24 for those responsibilities?

25 A. Not prior to the move but

1 during the move customer service reps helped
2 get me up to speed, and then Karen and I
3 talked a great deal about what the
4 requirements were. Again, I had a copy of
5 the CFR to refer to, knew what some of the
6 expectations were with regard to clearing a
7 222 form within 24 hours of shipment and
8 things like that.

9 Q. Okay. And so no formal
10 classroom training; more on-the-job training
11 type thing?

12 A. No, more of on-the-job
13 training, yes.

14 Q. Okay. And did you talk to
15 Mr. Welch at all in the transition to get any
16 guidance from him?

17 A. Yes.

18 Q. What can you recall in that
19 regard?

20 A. Sean and I were friends, so
21 when I had a question about something, I
22 would call him and try to bounce something
23 off of him, ask his opinion.

24 Q. Okay. Were there aspects of
25 DEA regulation or requirements that you

1 needed to be familiar with to perform your
2 customer service responsibilities that were
3 different from DEA requirements and
4 regulation that you needed to be familiar
5 with to perform your planning function?

6 MR. DAVISON: Objection. Form.

7 THE WITNESS: Yes.

8 QUESTIONS BY MR. GOTTO:

9 Q. And what are the differences
10 you can recall?

11 A. On the customer service side of
12 the business, your focus was on 222 forms,
13 making sure that the customers had them
14 before we could -- that we were in possession
15 of them before we could ship any product to
16 the customer.

17 On the planning side of the
18 business, the focus was more on quota. Can
19 we legally procure the raw materials,
20 manufacture the product and have it ready for
21 distribution.

22 Q. Okay. And the quota was
23 Mallinckrodt's quota, right?

24 A. Yes.

25 Q. Okay. And so tell me what a

1 222 form is.

2 A. A 222 form is issued by the DEA
3 to each registrant who purchases dosage or
4 API product. They fill out specifics with
5 regard to what product they want to purchase
6 and the quantity they want to purchase.

7 Once we receive that form, the
8 222 form number was entered into the system
9 to release the order. So that told everybody
10 it's legal, we have the 222 form, we can ship
11 this.

12 Then after the shipment is
13 executed, you go back to the form and you
14 fill out how much was shipped and when it was
15 shipped, and that form goes back to the DEA.

16 Q. Okay. So did a customer
17 provide a 222 form for each order?

18 A. Yes.

19 Q. Okay. And --

20 A. There were -- you could order
21 multiple products on each 222 form.

22 Q. Okay. Give me an example of
23 how that would work.

24 A. There were multiple lines on
25 the form, maybe eight lines, so I could order

1 oxycodone on one line, methadone on another
2 line, hydromorphone on another line. So once
3 each form tied back to an order -- and they
4 had to be a 100 percent match to be legal.

5 Q. So the 222 form, just trying to
6 understand, would it -- would it be with
7 reference to a specific dosage product or
8 would it be with reference to some quantity
9 of the API?

10 A. They're used for purchases of
11 both dosage and API. When you order dosage
12 products on a 222 form, you order it in
13 bottles or cases.

14 When you order API on a 222
15 form, it's ordered in grams or kilos.

16 Q. Okay. And so, for example --
17 let's talk first about a bulk order and how a
18 222 form would work.

19 A. Uh-huh.

20 Q. Would the 222 form be specific
21 to a particular API and identify a quantity
22 of that that could be ordered?

23 A. Each line would be a specific
24 API and quantity, but you could order
25 multiple molecules, like 2, 8, or however

1 many lines were on it. So you could order
2 morphine, oxycodone, you know, different
3 products on each 222 form.

4 Q. Okay. And as long as the
5 amount ordered for each of those products was
6 not greater than the amount set forth on the
7 222 form, that order could be fulfilled?

8 A. Yes.

9 Q. Okay. Now, let's talk about a
10 222 form in a dosage order.

11 A. Okay.

12 Q. What format would that take?
13 Would it, for example, identify specific --
14 say a 15-milligram tablet or 100-tablet
15 bottle of a 15-milligram product?

16 A. Correct. The order quantities
17 would typically be 12 cases of oxycodone
18 5/325. So a case might have been six
19 100-count bottles of oxycodone, where you've
20 got 5 milligrams of oxycodone and
21 325 milligrams of acetaminophen. So those
22 are ordered in cases, typically.

23 Sometimes smaller operations
24 like methadone clinics would order bottles of
25 methadone rather than cases because they

1 Ultimately, do you recall if
2 that process was adopted?

3 A. Yes.

4 Q. And so during the period you
5 were customer service manager for dosage, did
6 you receive a peculiar order report twice a
7 day?

8 A. Yes.

9 Q. Approximately how many peculiar
10 orders can you recall being included on a
11 peculiar order report?

12 A. I have --

13 MR. DAVISON: Objection to
14 form.

15 THE WITNESS: I don't know.
16 Not many, but I can't specify a
17 number.

18 QUESTIONS BY MR. GOTTO:

19 Q. Okay. But you would receive
20 the report twice a day, correct?

21 A. Yes.

22 Q. Were there times when the
23 report had no peculiar orders on it?

24 A. I don't recall.

25 Q. Okay. Would it be unusual if a

1 peculiar order report that you received with
2 respect to dosage had more than ten orders on
3 it?

4 MR. DAVISON: Objection to
5 form.

6 THE WITNESS: I don't know.

7 QUESTIONS BY MR. GOTTO:

8 Q. Okay. Would it be unusual if
9 it had more than 20 on it, 20 orders?

10 MR. DAVISON: Objection to
11 form.

12 THE WITNESS: I don't ever
13 recall a report having that many.

14 QUESTIONS BY MR. GOTTO:

15 Q. Okay. So as best you can
16 recall today, it would be unusual if it had
17 more than 20?

18 A. Yes. Yeah.

19 Q. But you don't recall if it
20 would be unusual if it had more than ten?

21 MR. DAVISON: Objection.

22 THE WITNESS: I don't recall it
23 ever having more than ten.

24 QUESTIONS BY MR. GOTTO:

25 Q. Okay. Do you recall a report

1 having more than five orders on it?

2 A. I don't recall.

3 Q. May have or may not --

4 A. May have, yeah.

5 Q. You just don't know?

6 A. I just don't know.

7 Q. Okay. So if you received the
8 report twice a day, you received ten reports
9 a week, right?

10 A. Correct.

11 Q. On a typical five-day workweek?

12 A. Yes.

13 Q. So is it fair to conclude that
14 over the course of a typical five-day
15 workweek you would have received peculiar
16 order reports indicating -- you know,
17 reporting some number of peculiar orders for
18 that week?

19 MR. DAVISON: Objection to
20 form.

21 THE WITNESS: Correct.

22 QUESTIONS BY MR. GOTTO:

23 Q. So when you received a peculiar
24 order report that identified one or more
25 peculiar orders, what steps did you take with

1 respect to that order?

2 A. I investigated in the sense
3 that who was the customer, what were the
4 circumstances, if I knew of them. We had
5 instances in snowstorms where trucks got
6 stuck for days at a time on a highway. And
7 so if I knew of a circumstance that justified
8 the reason for the additional order, or the
9 peculiar order, then I'd discuss it with
10 Karen and we would release the order. If
11 not, we kind of kicked it up the chain and
12 said, "I can't figure out why they're
13 ordering this," and then Karen would maybe
14 get with marketing or whatever to resolve the
15 problem.

16 Q. Okay. So once an order was
17 identified as peculiar -- and again, focusing
18 on dosage initially -- who had the authority
19 to authorize the filling of that order?

20 A. I did.

21 Q. Okay.

22 A. Or Karen, Bill Ratliff.

23 Q. Okay.

24 A. Any one of us.

25 Q. Okay. Were there times that

1 you can recall authorizing the fulfilment of
2 an order that had been identified as peculiar
3 without consulting with anyone else?

4 A. Yes.

5 Q. And what circumstances can you
6 recall?

7 A. I can't remember.

8 Q. Okay. May have been, for
9 example, the weather-related type thing that
10 you described?

11 A. Right. Yes.

12 Q. Do you ever recall a
13 circumstance, again, focusing on dosage,
14 where someone else, Ms. Harper or someone
15 else in the -- in the chain, authorized the
16 fulfilment of a peculiar order where you had
17 concerns that the issue as to whether it was
18 suspicious had not been thoroughly
19 investigated?

20 A. No.

21 Q. Now, let's turn to when you had
22 responsibility for API.

23 A. Uh-huh.

24 Q. Did you receive the report once
25 a day --

1 A. Yes.

2 Q. -- during that time?

3 A. Yes.

4 Q. Okay. And typically was there
5 at least one order reflected on a report?

6 A. I would say not daily, but
7 maybe over the course of a week there might
8 be a report, an order on the report.

9 Q. Okay. With respect to any
10 order that was reported as peculiar on the
11 bulk report, what steps would you take?

12 A. The same as with dosage.

13 Q. And did the same people have
14 authority to authorize the fulfilment of a
15 bulk order that had been identified as
16 peculiar as had that authority with respect
17 to dosage?

18 A. Yes.

19 Q. Do you know if there was -- or
20 do you recall there being any occasion in
21 which a bulk order was fulfilled -- a bulk
22 order that had been identified as peculiar
23 was fulfilled prior to the time a final
24 determination had been made as to whether it
25 was suspicious?

1 A. Uh-huh.

2 Q. -- what does "lines" mean in
3 this setting?

4 A. Lines would be -- or each
5 molecule strength would be a separate line on
6 an order.

7 Q. Okay. And so this is a
8 supplier that had experienced approximately
9 1560 specific items that were ordered as --
10 that were identified as at least potentially
11 suspicious out of approximately 13,000?

12 MR. DAVISON: Objection to
13 form.

14 THE WITNESS: Correct.
15 Correct.

16 QUESTIONS BY MR. GOTTO:

17 Q. Now, as to Mallinckrodt, in a
18 typical month on the dosage business, how
19 many lines per month would you expect would
20 be ordered?

21 MR. DAVISON: Objection to
22 form.

23 THE WITNESS: I have no idea.
24 A lot.

25

1 QUESTIONS BY MR. GOTTO:

2 Q. More than 13,000?

3 A. I don't know. I'd be guessing.

4 Q. Okay. And do you know in terms
5 of Mallinckrodt's experience, as far as
6 orders that were identified as peculiar,
7 whether its experience would approximate the
8 12 percent experience referenced here?

9 MR. DAVISON: Objection to
10 form.

11 THE WITNESS: I don't know.

12 QUESTIONS BY MR. GOTTO:

13 Q. Okay. You didn't personally
14 ever go back and do any sort of calculation
15 as far as what percentage of orders had been
16 identified as peculiar; is that fair?

17 A. Correct.

18 Q. And do you know if anyone else
19 at Mallinckrodt ever performed such a
20 calculation?

21 A. I don't know. In the very
22 beginning it was such a new program, I don't
23 think that anybody was doing it. And by the
24 time it had become an established program, I
25 had moved on, so I don't know if anybody did

1 that type of analysis or not.

2 Q. Do you think it's possible that
3 Mallinckrodt's dosage order volumes would
4 have exceeded 13,000 lines per month?

5 MR. DAVISON: Objection to
6 form.

7 THE WITNESS: I would say it's
8 conceivable.

9 QUESTIONS BY MR. GOTTO:

10 Q. During the period that you had
11 responsibility for dosage as customer service
12 manager, do you have any estimate as to the
13 number of peculiar orders that your staff had
14 capacity to evaluate on a daily basis?

15 A. Repeat the question, please.

16 Q. Sure.

17 While you were customer service
18 manager for dosage, do you have any estimate
19 of the number of peculiar orders that the
20 CSRs who reported to you would have capacity
21 to review on a daily basis, approximately?

22 A. My opinion would be that they
23 evaluated every order that they entered for
24 anomalies, and then if they felt that
25 something was out of sort or character,

1 they'd bring it to my attention.

2 Q. Okay. So they evaluated --
3 when you say "they evaluated every order," is
4 that independent of whatever algorithms were
5 put in place by the team?

6 A. Yes.

7 Q. And what were the criteria that
8 they used to conduct that evaluation,
9 independent of algorithms?

10 A. Our customer base was -- our
11 relationships had been very long-standing,
12 and the customer service reps were kind of
13 intimate with the customers. They knew
14 exactly what they ordered and what typical
15 quantities were and frequency. So if
16 something seemed out of the ordinary, they
17 would bring it up.

18 Q. Okay. And the -- were the
19 algorithms that the -- that the team adopted
20 in place during any portion of the time that
21 you had dosage responsibility as customer
22 service manager?

23 A. No, they were developed during
24 my tenure in that position.

25 Q. Okay. So during the time you

1 had responsibility for dosage, the
2 identification of orders as peculiar would
3 have been based entirely on your CSRs making
4 the sort of evaluation that you just
5 described a few moments ago?

6 A. Correct.

7 MR. DAVISON: Objection to
8 form.

9 QUESTIONS BY MR. GOTTO:

10 Q. A couple of paragraphs below
11 the one we were just looking at, there's one
12 that states, "Companies indicate that they
13 have employed the services of a statistician
14 to work with their IT professionals to
15 develop appropriate algorithms, et cetera,
16 for use in the code to identify the SOM
17 lines."

18 Do you see that?

19 A. Yes.

20 Q. Did Mallinckrodt, to your
21 knowledge, ever employ a statistician to work
22 in this regard?

23 A. Not that I'm aware of.

24 Q. If you turn to the second page
25 of Exhibit 6, the first paragraph, it says,

1 "When trying to normalize your data for
2 purposes of doing calculations to identify
3 anomalies, consider the base drug, API,
4 itself, rather than focusing on strengths and
5 doses per bottle."

6 Do you see that?

7 A. Yes.

8 Q. And did the algorithms that the
9 team ultimately adopted follow that -- that
10 direction?

11 A. Yes, they did.

12 Q. Okay. Down one, two, three,
13 four paragraphs from there, there's a
14 paragraph that says, "Are our customers aware
15 of the SOM requirements, question mark?
16 Conduct a prophylactic order" -- I'm sorry --
17 "prophylactic audit and confirm that they
18 have systems in place to call out deviations
19 on orders placed in their systems, paren,
20 their SOM processes and procedures."

21 Do you see that?

22 A. I do.

23 Q. Did Mallinckrodt ever conduct
24 such a prophylactic audit?

25 MR. DAVISON: Objection to